



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-D-0419]

Guidance for Industry on Acute Bacterial Exacerbations of Chronic Bronchitis in Patients With Chronic Obstructive Pulmonary Disease: Developing Antimicrobial Drugs for Treatment; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled “Acute Bacterial Exacerbations of Chronic Bronchitis in Patients With Chronic Obstructive Pulmonary Disease: Developing Antimicrobial Drugs for Treatment.” This guidance addresses FDA’s current thinking regarding the overall development program and clinical trial designs for drugs to support an indication for treatment of acute bacterial exacerbations of chronic bronchitis in patients with chronic obstructive pulmonary disease (ABECB-COPD), and finalizes the revised draft guidance issued on August 22, 2008.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the

SUPPLEMENTARY INFORMATION section for electronic access to the guidance document.

Submit electronic comments on the guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Joseph G. Toerner,
Center for Drug Evaluation and Research,
Food and Drug Administration,
10903 New Hampshire Ave.,
Bldg. 22, rm. 6244,
Silver Spring, MD 20993-0002,
301-796-1300.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled “Acute Bacterial Exacerbations of Chronic Bronchitis in Patients With Chronic Obstructive Pulmonary Disease: Developing Antimicrobial Drugs for Treatment.” The purpose of this guidance is to assist sponsors in the overall clinical development program of drugs to support an indication for the treatment of ABECB-COPD. This guidance finalizes the revised draft guidance published on August 22, 2008 (73 FR 49684), which in turn revised the draft guidance for industry entitled “Acute Bacterial Exacerbations of Chronic Bronchitis--Developing Antimicrobial Drugs for Treatment” published in 1998. Changes from the revised draft guidance are incorporated into the appropriate sections of the guidance and were based on comments submitted to the docket for the draft guidance. In addition, developments in scientific and medical information and

technology in the treatment of ABECB-COPD are reflected in this guidance. This guidance fulfills the requirement set forth in the Food and Drug Administration Amendments Act of 2007 that directed FDA to update the ABECB-COPD guidance within 5 years.¹ This guidance also responds to the requirement set forth in the Food and Drug Administration Safety and Innovation Act of 2012 that FDA review guidances for the conduct of clinical trials with respect to antibacterial and antifungal drugs and revise such guidances as appropriate.²

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on developing drugs for the treatment of ABECB-COPD. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 312 have been approved under 0910-0014; the collections of information in 21 CFR part 314 have been approved under 0910-0001; and the collections of information referred to in the guidance for clinical trial sponsors entitled "Establishment and Operation of Clinical Trial Data Monitoring Committees" have been approved under 0910-0581.

III. Comments

Interested persons may submit either written comments regarding this document to the Division of Dockets Management (see ADDRESSES) or electronic comments to

¹ See Title IX, section 911, of the Food and Drug Administration Amendments Act of 2007 (Public Law 110-85).

<http://www.regulations.gov>. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: September 25, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012-24035 Filed 09/28/2012 at 8:45 am; Publication Date: 10/01/2012]

² See Title VIII, section 804(a)(1), of the Food and Drug Administration Safety and Innovation Act of 2012 (Public Law 112-144).